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Attorney Docket No. MP/147

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD
OF PATENT APPEALS
AND INTERFERENCES**

Applicant : Laguna et al.
Appl. No. : 09/384,900
Filed : August 27, 1999
Title : An Improved Balloon Catheter and
Method of Mounting Same

Group Art Unit : 3763
Examiner : Nguyen, Anh Tuan Tuong

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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addressed to: MS Appeal Brief - Patents,
Commissioner for Patents, P.O. Box 1450,
Alexandria, VA 22313-1450, on September
10, 2004.*

Melanie Williams
Melanee Williams

APPEAL BRIEF UNDER 37 C.F.R. § 1.192

Sir:

Three copies of this Brief are provided herewith.

Applicants request that the fee for the Appeal Brief be taken from our Deposit

Account No. 07-1729.

This appeal is taken from the Office's decision dated May 17, 2004, finally rejecting claims 24-42. The Notice of Appeal was timely filed on July 16, 2004.

Real Party in Interest

The above-referenced application names Alvaro J. Laguna and Carey V. Campbell as co-inventors. The application has been assigned to Gore Enterprise Holdings, Inc., 551 Paper Mill Road, P.O. Box 9206, Newark, Delaware 19714; a subsidiary of W. L. Gore & Associates, Inc., 550 Paper Mill Road, Newark, Delaware 19714. The assignment was recorded in the U.S. Patent and Trademark Office on August 27, 1999 at Reel: 010233 and Frame: 0897.

Related Appeals and Interferences

There are no other appeals or interference proceedings pending in the above-referenced application.

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Status of Claims

Claims 1-42 were originally filed in the above-referenced application. Claims 1-23 were cancelled without prejudice in response to a restriction requirement. Claims 24-42 are pending in the application and are the subject of the present appeal.

Status of Amendments

There have been no amendments filed subsequent to the current final rejection.

Summary of the Invention

The present invention is an improvement in the construction of a distensible sleeve to be mounted on a catheter shaft in order to create a medical catheter balloon. The invention recognizes a problem in prior art distensible balloon materials that have proven difficult to mount to catheter shafts in a reliable fluid-tight manner. Referring to Figure 3, the invention comprises a sleeve (12) formed from a distensible material that prior to being mounted on a catheter shaft (14, 16) has one or both of its ends (28, 30) rendered non-distensible. See Application, at 6, lines 9 to 32. By providing a balloon sleeve with its ends pre-treated to be non-distensible prior to being mounted on a catheter shaft, the present invention has proven to be faster and easier to mount and more reliable in operation than previous distensible balloon designs. See Application, at 3, lines 16 to 19; 5, lines 24 to 27; 9, lines 13 to 16. This is because the prior balloon designs essentially required distensible material to be inefficiently rendered non-distensible in the process of mounting the distensible material onto the catheter shaft.

Issue

Whether claim 24 is anticipated under 35 U.S.C. §102(b) by U.S. Patent 5,728,066 to Daneshvar or U.S. Patent 5,718,680 to Kraus et al.

Grouping of Claims

In order to make the appeal process as efficient as possible, applicants request that the grounds for rejection be considered against independent claim 24 alone. For the purposes of this appeal, the remaining claims of the group will stand or fall together with the independent claim.

Argument

The examiner has rejected claims 24-26 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent 5,728,066 to Daneshvar ("Daneshvar patent") and claims 24, 25, 29, 32-34, 37, and 40-42 as being anticipated by US Patent 5,718,680 to Kraus et al. ("Kraus et al. patent"). The remaining claims stand rejected under 35 U.S.C. §103(a) as obvious over the Daneshvar patent in combination with U.S. Patent 5,843,116 to Crocker et al. ("Crocker et al. patent") or U.S. Patent 5,766,201 to Ravenscroft et al. ("Ravenscroft et al. patent"). As is explained below, the Daneshvar and Kraus et al. patents in no way teach the claimed elements of the present invention, either alone or in combination with the other references of record. Reversal of the examiner's decision and allowance of the present application are respectfully requested.

The present invention as claimed differs from the prior art because the balloon sleeve of the present invention is rendered non-distensible prior to being formed into a balloon by mounting on the catheter shaft. Claim 24 defines the present invention as follows:

A sleeve adapted to be mounted on a catheter shaft so as to be formed into an inflatable balloon comprising
the sleeve having a first end, a second end, and a middle section;
wherein prior to being formed into the balloon by mounting on the catheter shaft at least one of the ends is non-distensible while the middle section of the sleeve is distensible.

This claim clearly defines over all of the cited references.

The examiner asserts that "Daneshvar teaches a balloon that is slidable along a catheter (col. 3, lines 21-25). Daneshvar further teaches that the balloon does not leak between itself and the catheter that it is mounted on (col. 9, lines 40-45)." Office Action of September 8, 2003, at 2. This is not a fair application of the Daneshvar patent against the present invention as claimed.

The Daneshvar patent does teach that its balloon (or "resistance unit") can be formed to slide along the catheter shaft (or "body") of its device. However, the balloon so formed is not a balloon sleeve with non-distensible ends, but, rather, a completed balloon device that can be moved along the catheter shaft after the completed balloon has been formed. In particular, Daneshvar teaches:

Importantly, the balloon or the resistance of these unit [sic] may be made to slide on the catheter and to be placed on a proper area of the catheter prior to use. In this model, the balloon will have tubing in its center that allows the balloon to be created and to move along the length of the catheter.

Daneshvar patent, at Col. 16, lines 44-49 (emphasis added). Thus, in order to allow the balloon to move along the length of his catheter shaft, Daneshvar must provide internal tubing around which the exterior of the balloon is formed. Accordingly, any non-distensible ends that may be formed in this process will be created only after the sealed balloon is formed in conjunction with the center tubing. Nothing in the Daneshvar patent in any way teaches or suggests creating a balloon sleeve that has non-distensible ends prior to being sealed into a final balloon construct. Fairly read in light of this teaching, the Daneshvar patent simply does not meet the claimed limitations of the present invention.

The Kraus et al. patent is also cited for the proposition that it "...teaches all the claimed subject matter including the balloon being attached to a non-distensible member (inner tube 21) to render the ends non-distensible" Office Action of September 8, 2003, at 2. However, just like the Daneshvar patent, Kraus et al. form a balloon over an internal tube before they render either end of the external balloon sleeve non-distensible. Specifically, Kraus et al. teach "The sheath 22 of the balloon is sealed around both ends of the internal tubular member 21 to form an inflatable cavity 23 which encircles the tubular member." Col. 3, lines 51-53 (emphasis added). Kraus et al. do not teach rendering the ends of their balloon sleeve non-distensible prior to forming the balloon itself.

With respect to both the Daneshvar and Kraus et al. patents, the center "tubing" and "internal tubular member" are essentially short catheter shafts around which the catheter balloons are formed. Just as is required with full-length catheters in conventional statically mounted balloons, these internal tube structures are necessary to convert the external sleeve material into a sealed balloon structure.

Claim 24 is specifically directed to a "sleeve" and not a completed balloon, and then it requires that at least one of the ends of the separate distensible balloon sleeve is rendered non-

distensible "...prior to being formed into the balloon...." None of the references of record in any way teaches or suggests a balloon sleeve of this nature.

It is well established that anticipation under 35 U.S.C. §102(a) or (b) requires that all elements the claimed invention must be found in a prior, publicly available product or described in a single reference. See, e.g., Richardson v. Suzuki Motor Co., Ltd., 868 F.2d 1226, 1236 (Fed. Cir.), cert. denied, 493 U.S. 853 (1989); Akzo N.V. v. U.S. Intern. Trade Com'n, 808 F.2d 1471, 1479 (Fed. Cir. 1986), cert. denied, 482 U.S. 909 (1987). Neither the Daneshvar patent nor Kraus et al. patent teaches a stand alone balloon sleeve that is distensible in its middle section and non-distensible on at least one of its ends prior to being formed into a balloon. Not only do these patents not teach the claimed sleeve of the present invention, they are also devoid of any recognition that there might be some advantage gained by rendering the ends of a balloon sleeve non-distensible prior to forming a balloon. The cited references are not anticipatory of the present invention as claimed and provide no teaching or suggestion that might lead one skilled in the art to reach the solution of the present invention as claimed.

With respect to the additional references used to reject the dependent claims, these patents do not correct the deficiencies already discussed with respect to the Daneshvar and Kraus et al. patents.

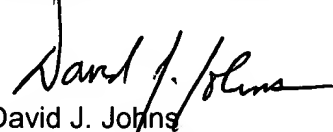
The Crocker et al. patent is directed to providing "expansion-limiting bands" along the length of an expandable balloon to create a balloon that has different "zones" of expansion along its length. The Crocker et al. patent neither teaches nor suggests that a balloon material should be rendered completely non-distensible at its ends prior to mounting on a catheter shaft. Combining the Daneshvar and Crocker et al. patents neither teaches nor suggests the present invention as claimed.

Likewise, the Ravenscroft et al. patent teaches wrapping a catheter shaft with an elastomeric (distensible) tape that is then wrapped around a non-distensible balloon material.

Again, this patent does not teach or suggest that a balloon material should be rendered completely non-distensible at its ends prior to mounting on a catheter shaft. It does not correct the deficiencies of the Daneshvar or Kraus et al. patents with respect to the present invention as claimed.

Accordingly, claim 24 of the present application is not anticipated under 35 U.S.C. §102(b) by either the Daneshvar or Kraus et al. patents or any of the other references of record. Reversal of the examiner's rejection is respectfully requested.

Respectfully submitted,



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Date: 9/10/04



SN 09/384,900

APPENDIX A -- CLAIMS ON APPEAL

24. A sleeve adapted to be mounted on a catheter shaft so as to be formed into an inflatable balloon comprising

the sleeve having a first end, a second end, and a middle section;

wherein prior to being formed into the balloon by mounting on the catheter shaft at least one of the ends is non-distensible while the middle section of the sleeve is distensible.

25. The sleeve of claim 24 wherein the sleeve is mounted on a catheter shaft to form an inflatable balloon.

26. The sleeve of claim 25 wherein the sleeve forms a liquid-tight seal at the ends to the catheter shaft.

27. The sleeve of claim 24 wherein the at least one end is tape wrapped to render it non-distensible.

28. The sleeve of claim 24 wherein the at least one end has a coating to render it non-distensible.

29. The sleeve of claim 24 wherein the at least one end has a modified structure that renders it non-distensible.

30. The sleeve of claim 24 wherein the at least one end is covered with an essentially non-distensible material to render it non-distensible.

31. The sleeve of claim 30 wherein the essentially non-distensible material comprises a reinforcing collar.

32. The sleeve of claim 24 wherein the at least one end is attached with adhesive to a non-distensible material to render it non-distensible.

33. The sleeve of claim 24 wherein the sleeve comprises a fluoropolymer.

34. The sleeve of claim 33 wherein the fluoropolymer comprises a polytetrafluoroethylene.

35. The sleeve of claim 25 wherein the at least one end is tape wrapped to render it non-distensible.

36. The sleeve of claim 25 wherein the at least one end has a coating to render it non-distensible.

37. The sleeve of claim 25 wherein the at least one end has a modified structure that renders it non-distensible.

38. The sleeve of claim 25 wherein the at least one end is covered with an essentially non-distensible material to render it non-distensible.

39. The sleeve of claim 38 wherein the essentially non-distensible material comprises a reinforcing collar.

40. The sleeve of claim 25 wherein the at least one end is attached to a non-distensible material to render it non-distensible.

41. The sleeve of claim 25 wherein the sleeve comprises a fluoropolymer.

42. The sleeve of claim 41 wherein the fluoropolymer comprises a polytetrafluoroethylene.



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10, 2004.*

Melanee Williams

Melanee Williams

LETTER OF TRANSMITTAL

Dear Sir:

Applicants enclose the following papers for filing in the U. S. Patent and Trademark Office
in connection with the above-identified Patent Application:

1. Three (3) Copies of Appeal Brief under 37 CFR 1.192 (6 pages each; 18 pages total).
2. Three (3) Copies of Appendix A Claims on Appeal (2 pages each; 6 pages total).

**The Commissioner is hereby authorized and requested to charge all fees due under
section 1.17 during the pendency of this application to our Deposit Account No. 07-1729.**

Respectfully submitted,

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